GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:44
ANSWERED ON:22.11.2006
QUALITY OF DRUGS
Vallabbhaneni Shri Balashowry

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether there is any mechanism to monitor the quality and standard of drugs in the country;

(b) if so, the details thereof; and

(c) if not, the reasons therefor?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAMADOSS)

(a) & (b) : In order to regulate the quality and standard of drugs manufactured in the country, the Government has prescribed appropriate provisions and requirements under the Drugs and Cosmetics Act, 1940 and the Rules made thereunder which have been amended from time to time. This includes laying down quality standards and minimum requirements for undertaking manufacture of drugs including requirements of Good Manufacturing Practices, inspection of manufacturing units to ascertain the status of their compliance to GMP and monitoring of quality by random sampling of drugs from the manufacturers as well as from the market.

The provisions related to manufacture and sale of medicines in the country are enforced by State Governments through their respective Drugs Control Organisations. The respective State Licensing Authorities may initiate appropriate action in respect of violation of various provisions depending upon nature and severity of such violations.

(c): Does not arise.